

REMARKS

Status of the Claims and Amendment

Claims 1-6 are all the claims pending in this application. Claims 1-5 are withdrawn from consideration.

Response to Claim Rejections Under 35 U.S.C. § 103

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pugliese (U.S. Patent No. 6,596,289 B1), in view of Tadashi Hase *et al.* (Anti-Obesity Effects of Tea Catechins in Humans, 2001, *Journal of Oleo Science*, 50(7): 599), further in view of JP 10234968 and JP 2000-229827 with Max (U.S. Patent No. 6,638,545).

Pugliese is asserted for teaching a treatment for cellulite that consists of ingredients that may be applied topically, either in a cream, lotion, or gel. The Examiner asserts that the ingredients may be affixed to a garment, such as panty hose or a stocking, in micro-encapsulated form; or they may be applied as a material patch, or plaster, either in a gel form or cloth supported form. The Examiner asserts that formulation comprises an oil-in-water emulsion that comprises genistein, L-carnitine, and caffeine.

Hase is asserted for teaching the anti-obesity effects of tea catechins in humans, in which catechin is administered to male subjects at 118.5 mg and 483.0 mg a day for 12 weeks. At 12 weeks, a reduction in weight, BMI, waist circumference, body fat ratio, abdominal fat and total cholesterol, glucose, insulin, PAI-1 in serum was observed in comparison to values at 0 week.

JP 10234968 is asserted for teaching an anti-obesity composition comprising theanine. In which the content of the theanine in the composition is preferably from 0.00025 to 100% by weight, or more preferably 0.005 to 100% by weight.

JP 2000-229827 appears to be asserted for teaching that external skin preparations may further comprise as medicinal components catechin and derivatives such as xanthin, theophylline, caffeine, and theanine, and that catechin, theanine, and caffeine can be used in formulations for external skin application as a lotion or ointment. The Examiner appears to assert that JP 2000-229827 teaches that the skin external preparation may contain 0.0005-5 weight percent of the components, and formulated as a lotion, cream, ointment etc.

Max appears to be asserted by the Examiner for combining the treatment of obesity and cellulite because the Max teaches a method for treatment of cellulite, obesity or excess weight. Specifically, the Examiner asserts that Max teaches that once obesity is treated cellulite is also treated.

Thus, the Examiner appears to conclude that one of ordinary skill in the art would have been provided with instruction and motivation to use theanine, genisteine, L-carnitine, catechin and caffeine to produce a composition that has a slimming effect as claimed so that the claimed invention would have been *prima facie* obvious.

In response, Applicants assert that for at least the reasons discussed below, the Examiner has failed to establish a *prima facie* case of obviousness.

The Examiner has failed to demonstrate how one of ordinary skill in the art would have been motivated or guided to combine the cited references as asserted in order to obtain the claimed composition. In this respect, the Examiner is reminded that just because the aspects of the claimed invention were individually known in the art, this is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993). As noted by the Board of Appeals and Interferences in *In re Whalen* (BPAI, July 23, 2008), the BPAI interpreted the

Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) to mean that obviousness cannot be proven merely by showing that the elements are known in the art, there must be some apparent reason to combine the known elements in the fashion claimed." *Id.* at 1741.

In the present case, although the active ingredients are individually known in the art, none of the cited references teach or suggest that the individual components may be combined in the manner asserted by the Examiner to achieve the claimed anti-cellulite composition. In fact, the Examiner's conclusion of obviousness is solely based upon improper hindsight gleaned from Applicants' present disclosure.

With regard to Pugliese, the Examiner has cited to a "paragraph 0022" (see bottom of page 3 of present Office Action) that is not found in the reference as Pugliese is U.S. Patent No. 6,596,289 that does not include paragraph numbering. Also, contrary to the Examiner's assertions in the paragraph bridging pages 3-4 of the present Office Action, claim 8 of Pugliese is not directed to a method of treating "cellulitis" in women wherein the application formulation comprises an oil-in-water emulsion. In this regard, "cellulitis" is a severe inflammation of dermal and subcutaneous layers of the skin that should not be confused with "cellulite." Also, the cellulitis patient population does not overlap with the cellulite subject population. Similarly, claims 4, 5 and 7 of Pugliese are not characterized as asserted by the Examiner at page 4 of the present Office Action. Accordingly, Pugliese does not teach or suggest the use of L-carnitine with regard to the treatment of cellulite.

Nevertheless, Applicants note that Pugliese is directed to an anti-cellulite pantyhose that is chemically treated with polyethylenimine (PEI) and xanthines such as theophylline acetate (THA) to allow gradual release of THA to the wearer's skin so that "[o]ver time, the THA has

the effect of reducing cellulite.” See column 3, lines 2-5 and lines 28-38 of Pugliese. Although Pugliese teaches that genistein may be used as an active ingredient in the pantyhose, Pugliese explicitly does **not** teach combination of genistein with a xanthine such as caffeine. In this respect, there is only a single disclosure of caffeine in Pugliese as a “common xanthine” (see column 1, line 29 of Pugliese). Rather, Pugliese explicitly discourages the combination of genistein with a xanthine because Pugliese states that “AA [(ascorbic acid)], LA [(lipoic acid)], and genistein, are suitable *alternatives to the other active ingredients of this invention, namely theophylline* salts and silantriol [emphasis added].” See column 9, lines 6-9 of Pugliese. Also, the only combinations that Pugliese teaches is that of genistein with ascorbic acid (AA) or lipoic acid (LA) (see column 3, lines 61-64 of Pugliese) or (2) theophylline with silanols, like silantriol (see column 3, line 65 to column 4, line 2 of Pugliese). Accordingly, Pugliese does not teach L-carnitine, nor that a xanthine such as caffeine and genistein should be combined or included in a single composition for the treatment of cellulite. Instead, only compositions containing either theophylline (a xanthine) *or* genistein are taught to be incorporated in pantyhose with PEI as a binding agent.

The teachings of Hase is insufficient to cure the deficiencies of Pugliese because the Examiner appears to rely solely on the English abstract of Hase for teaching that tea catechins have anti-obesity effects in humans. Although Hase teaches that tea catechin is administered at a low and high dose to produce the effects described, Hase does not teach or suggest that tea catechin may be administered externally on the skin as an anti-cellulite composition. One of ordinary skill in the art would not understand from the limited disclosure in Hase to combine tea catechins with any other ingredients, much more identify that the tea catechins may be combined specifically with theanine, genistein, L-carnitine, and caffeine as in the claimed anti-cellulite

composition. Accordingly, the Examiner has failed to explain how the anti-obesity effects described by Hase would be extrapolated by one of ordinary skill in the art to obtain an anti-cellulite composition for external skin application as claimed for the purpose of achieving an anti-cellulite effect.

With regard to JP 2000-229827, Applicants assert that although JP 2000-229827 discloses a skin external preparation, the preparation contains tomato color with lycopene complex as an active substance. See [Claim 1], [Claim 2], paragraph [0001] and paragraph [0012] of JP 2000-229827. Further, the external skin preparation of JP 2000-229827 is explicitly taught to be used to “prevent generation of lipid peroxide within the skin surface and the skin and the inflammation of skin, melanism, a wrinkle, sagging, etc. and which have the outstanding skin aging preventive effect, concerning the skin external preparations containing tomato color.” See paragraph [0001] of JP 2000-229827. In contrast, the present invention is directed to an anti-cellulite composition. Also, even though catechin, caffeine, theophylline, and theanine are individually taught, the ingredients are listed under separate laundry lists of active ingredients. Catechin is listed as a an “active oxygen remover” (see paragraph [0016] of JP 2000-229827). Caffeine and theophylline are listed as “cell activators” in which they are characterized as “[n]ucleic acid related substances which are xanthine and those inductors, such as caffeine and a theophylline” (see paragraph [0024] of JP 2000-229827). Similarly, theanine is listed in a separate list as a “moisturizer” (see paragraph [0027]). There is nothing in JP 2000-229827 to guide or motivate one of ordinary skill in the art to specifically identify and select. i.e., single out the claimed active ingredients from the laundry lists disclosed in JP 2000-229827, and to combine them in an anti-cellulite composition for external skin application as claimed. The present case is similar to *Ex parte McDonnell* (BPAI 2004) in which the BPAI reversed the

Examiner's rejection under 35 U.S.C. 103(a) based upon references that provided a generic "laundry list" encompassing the components of the claimed product.¹

JP 10234968 is even less relevant because contrary to the Examiner's assertions, JP 10234968 is non-analogous art. JP 10234968 relates to a pachinko machine with a ball exhaust that discharges a loan ball that a game person borrow. See paragraph [0001] of the English translation of JP 10234968 provided with the present Office Action). Accordingly, there is nothing in JP 10234968 that is directed to an anti-obesity composition comprising theanine in an amount asserted by the Examiner. However, *arguendo*, even if such a composition was taught, which it is not, such a teaching would not be sufficient to guide one of ordinary skill in the art to include theanine with any other ingredients, much more lead one of ordinary skill in the art to specifically select genistein, L-carnitine, catechin, and caffeine as active ingredients to combine with theanine to obtain an anti-cellulite composition for external skin application as claimed.

Rombi (which is referred to as "Max" by the Examiner) does nothing to cure the deficiencies of the references discussed above because Rombi is merely relied upon for teaching a "method for the treatment of cellulite, obesity or excess weight". See claim 1 of Rombi. However, the Examiner has taken this recitation in claim 1 of Rombi out of context because the rest of the claim recites that the treatment comprises administering "a food supplement comprising an effective amount of a grape extract, said extract being rich or enriched in

¹ The BPAI found that the examiner relied upon the primary reference, Zhang for disclosing the basic adenoviral construction of the invention and relied on the other references to meet the limitations of the dependent claims. However, the examiner did not cite any evidence or provide any reasoning to show that those skilled in the art would have found it obvious to combine a specific promoter (or class of promoters) with a proapoptotic member of the Bcl-2 gene family. In other words, the examiner provided no reasoning as to how one of skill in the art would have been motivated to choose and combine the different elements that are separately disclosed.

polyphenols and having a proportion of from 30% to 90% by weight of polyphenols and from 0.001% to 0.1% by weight of trans-resveratol.”

Furthermore, neither Pugliese, Hase, JP10234968, JP 2000229827 nor Rombi, separately or in combination, teach or suggest all of the claim limitations. None of the references cited teach or suggest (1) L-carnitine nor (2) the claimed amount of 0.0001 wt% to 20w% of the total weight of the composition (consisting of theanine, genistein, L-carnitine, catechin, and caffeine).

Thus, there would have been no motivation or reason for one of ordinary skill in the art to combine the teachings of Pugliese, Hase, JP10234968, JP 2000229827 and Rombi as asserted by the Examiner. However, even if one of ordinary skill in the art was somehow motivated to make such a combination, the combination of Pugliese, Hase, JP10234968, JP 2000229827 and Rombi would not result in the presently claimed anti-cellulite composition for at least the above reasons. That is, the combined references do not teach or suggest each and every claim limitation, nor motivate one of ordinary skill in the art to make the presently claimed anti-cellulite composition consisting of theanine, caffeine, genisteine, L-carnitine, and catechin as active ingredients wherein the combination of theanine, caffeine, genisteine, L-carnitine, and catechin is present in an amount of 0.0001 wt% to 20 wt% of the total weight of the composition, and wherein the external skin application composition is a composition selected from the group consisting of a lotion, ointment, gel, cream, patch, and spray.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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